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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,158	12/20/2001	Isabella Caniggia	11757.38USD1	4218

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EXAMINER	
ANDRES, JANET L	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,158	CANIGGIA ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *3-19* is/are withdrawn from consideration.

5)☒ Claim(s) *20-23 and 26-30* is/are allowed.

6)☒ Claim(s) *1,2,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II, claims 1, 2, and new claims 20-30, drawn to diagnosis of a condition requiring regulation of trophoblast invasion by detection of HIP-1α and of oxygen tension, and species election of antisense, is acknowledged. Applicant's traversal on the basis that restriction within a claim is improper has been fully considered but has not been found to be persuasive. In re Weber does not find restriction within a single claim improper unless such restriction would prevent further examination in divisional applications: "On this appeal from the rejection of claims 1-6 we do not have before us a restriction requirement under §121. Such a requirement would not have been appealable to the board. We have before us an appeal from affirmance of a rejection." The instant restriction requirement is not a rejection of the non-elected inventions and is thus deemed proper and made final. Claims 1-30 are pending in this application. Claims 3-19 are withdrawn from consideration as being drawn to a non-elected invention. Claim 1 as it pertains to diagnosis, claim 2, and claims 20-30 are under examination. The requirement for an election of species is withdrawn in view of Applicant's election of diagnostic methods, since the various means of detecting polynucleotides and polypeptides are standard in the biomedical arts.

Specification

2. The specification is objected to because this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. The application includes sequences that do not have

a sequence id number. See the Brief Description of the Drawings, which does not provide identifiers for the sequences in the figures, as well as p. 6, line 26, p. 12, lines 18-19, p. 16, lines 21 and 23, p. 21, lines 20, 22, and 26, and p. 22, lines 8-16. Applicant must provide a computer readable form (CRF) copy of the "Sequence Listing", a paper copy of the "Sequence Listing" as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diagnosis of preeclampsia by detection of placental expression of HIF-1α, does not reasonably provide enablement for diagnosis by modulation of HIP-1α or of oxygen tension, diagnosis of any other condition, or for methods of measuring HIF-1α in other tissues. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte*

Forman, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands,* 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 1 as restricted is drawn to a method for detecting a condition requiring regulation of trophoblast invasion comprising modulating HIF-1α or oxygen tension. No guidance is present in the specification to indicate how this might be accomplished; there is no direction as to how modulating a factor or a condition would allow diagnosis of a disease. Thus one of skill would not be able to practice the invention as claimed.

Claims 1and 2 are broadly drawn to encompass any condition requiring regulation of trophoblast invasion. However, the specification has not provided sufficient guidance to enable one of skill in the art to predictably diagnose any condition other than preeclampsia. The specification provides no guidance as to what other conditions require such regulation, or how HIP-1α might be involved. There is no guidance in the specification to indicate that the expression pattern of HIP-1α is predictive of any other disease. The prior art fails to provide compensatory teachings; what was known was that low oxygen tension was associated with preeclampsia (see Genbacev et al., 1996, J. Clin Inves., vol. 97(2), pp. 540-550). Thus without further guidance, one of skill would not be able to predict that HIP-1α expression would be useful for the detection of any condition other than preeclampsia.

5. Claims 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. Claims 24 and 25 are drawn to methods of detecting HIF-1α by detecting its interaction with other DNA molecules. Such molecules are only mentioned in the specification (p. 7, lines 33-36); there is no guidance as to their nature or how they might be used to identify HIF-1α.

Without direction sufficient to render such other uses predictable, it would require undue experimentation for the skilled artisan to practice the invention as broadly claimed.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. A correlation step, describing how the results of the assay allow the determination of success, is omitted.

CLAIMS 1, 2, 24, AND 25 ARE REJECTED. CLAIMS 20-23 AND 26-30 ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
3 March 2004